## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MARYLAND

VEIN & WELLNESS GROUP, LLC,

Plaintiff,

v.

Case No. 1:22-cv-00397-JMC

XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services,

Defendant.

## PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION FOR LEAVE TO FILE <u>SUR-REPLY</u>

Plaintiff Vein & Wellness Group's (VWG) opposes the Secretary's request to submit a surreply. The Secretary has not made the required showing and what the Secretary proposes is simply unlimited briefing.

Initially, the Secretary alleges that a sur-reply should be allowed because "Plaintiff mischaracterizes the law ..." Mot. at ¶4. That is such a generalized position that it could be asserted on every filed paper and there would be endless sur-replies.

The Secretary's next alleged basis is that VWG raised new arguments in its reply. Mot. at ¶¶4 and 5. In particular, the Secretary alleges that VWG had not previously argued that the Secretary's assertion would allow the MAC to craft denials on any basis while providers would be precluded from submitting evidence to rebut it. In its motion papers, VWG argued that both the issues and evidence at the ALJ stage are limited and that those same restrictions apply at the MAC stage because the ALJ cannot err by failing to consider issues/evidence that are not properly before him. See Dkt. #24 at 3 ("limitation on submitting/consideration of evidence not presented to the

QIC"), 14 ("critical that the insured/provider have notice of any bases for denial so that, prior to the QIC decision, the insured provider can submit any relevant evidence"); 15; 22 ("Having had no notice, VWG was precluded from submitting evidence after the QIC's decision and could not submit evidence for the first time to the MAC.").

In opposition, citing *inter alia*, 42 U.S.C. § 1395ff(b)(3),<sup>1</sup> the Secretary contended that providers could not submit evidence that was not presented to the QIC. *See* Dkt. #27 at 1, n. 1 ("healthcare providers may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the QIC unless there is good cause") (cleaned up). Thus, because VWG had not submitted evidence regarding the newly alleged lack of scientific merit of the MOCA procedure to the QIC, the Secretary argued that VWG was "statutorily prohibited from presenting any new information in support of its position." *Id*. In this regard, the Secretary's arguments were in full accord with VWG's, in both VWG's motion papers (Dkt. #24 at 3, 14-15) and VWG's reply (Dkt. #30 at 2-3). Given that, clearly, the limitation on new evidence was not a "new argument" raised in VWG's reply.

With regard to the scope of issues the MAC may consider, VWG argued that - just like the ALJ - the MAC is limited to those issues identified in the request for an ALJ hearing – which stems from the issues identified as the basis for rejection by the QIC. *See* Dkt. #24 at 3, 14-15.<sup>2</sup> It was

<sup>&</sup>lt;sup>1</sup> VWG understands that the restriction of 42 U.S.C. § 1395ff(b)(3) applies only during the proceedings before the Secretary and does not govern proceedings before this Court. Thus, this Court may properly consider the decisions on which collateral estoppel is based even though they were not submitted to the QIC. In any event, the "good cause" required by the statute would exist because the decisions on which collateral estoppel rests did not exist before the QIC made its reconsideration decisions. That is, the decisions on which collateral estoppel are based issued on July 12, September 14, and September 30, 2021 (see Dkt. #24 at 8-9; Exhibits A, B, and C), while the last QIC reconsideration decision issued on March 6, 2017 (AR289, 305).

<sup>&</sup>lt;sup>2</sup> This ties into the statutory requirement that QIC decisions be fully explained. See 42 U.S.C. § 1395ff(c)(3)(E)

the Secretary that argued that the MAC was not so limited and could decide matters based on entirely new issues. See Dkt. #27 at 4 ("the Medicare Appeals Council was not limited to addressing exclusively the issues raised before the ALJ.") (emphasis in original). Instead, the Secretary contended that the MAC could consider any exception raised in CMS' request for "own motion review." Id. In Reply, VWG reiterated its own position and pointed out the absurd results of the Secretary's position in that the insureds/providers would be precluded from introducing evidence to rebut issues first raised at the MAC level. Again, VWG did not make a "new argument." Either VWG made the same argument or, at worst, VWG responded to an argument raised by the Secretary. When the Secretary makes an argument and VWG responds, VWG does not make a "new argument" in its Reply. Thus, again, there is no basis for a sur-reply.

Next, the Secretary alleges that "Plaintiff also raises the misleading contention that the Secretary should be legally bound by erroneous administrative decisions by way of collateral estoppel and that the Appropriations Clause does not prohibit such collateral estoppel." Mot. at ¶5. Of course, collateral estoppel was not a new argument. That was the basis of Plaintiff's motion. See Dkt. #24 at 5-7; 16-19. With regard to the Appropriations Clause, that was raised by the Secretary as one basis for opposition to Plaintiff's assertion of collateral estoppel. See Dkt. #27 at 16. When VWG responds to an argument raised by the Secretary, VWG does not make a "new argument." Indeed, were that the case, non-movants would always have sur-replies. Clearly, that is not the standard.

Finally, the Secretary contends "Plaintiff erroneously argues the Secretary has conceded various points, when in fact the Secretary did not concede – and specifically addresses – each of these points in its briefing." Mot. at ¶5. Respectfully, Plaintiff fails to see how, under any standard, this could be the basis for a sur-reply. Putting that aside, the Secretary's contention is simply false.

In its motion papers, Plaintiff reviewed and made a showing as to each of the five elements of collateral estoppel. *See* Dkt. #24 at 17-19. In opposition, the Secretary reviewed the same five elements and contended: "[VWG] has not carried it burden on the first, second, and fifth elements." *See* Dkt. #27 at 18. Thus, the Secretary did not challenge VWG's showing as to elements three ("determination of the issue was a critical and necessary part of the decision in the prior proceeding") and four ("the prior judgment must be final and valid"). The Secretary made no effort to show that these elements were missing. Indeed, the word "critical" appears in the Secretary's brief only when reciting the elements of collateral estoppel. Accordingly, in its Reply, VWG noted that these elements were conceded. As to "full and fair opportunity to litigate", as VWG noted in its papers, the Secretary did not contest that he had such an opportunity. Instead, the Secretary contended that there were various (false) reasons why he chose not to take advantage of that opportunity. VWG stands by its belief that the Secretary conceded this element as well. In any event, again, the Secretary has not made the showing required for a sur-reply.

Rather than being sandbagged by "new arguments" raised for the first time in a Reply, this case is exactly what it seems. The non-movant wanted to supplement his papers and needed an excuse to do so. Thus, the non-movant falsely asserts that "new arguments" and submits a supplemental brief. That approach to litigation should be rejected.

Nevertheless, VWG notes the irony of the Secretary contending that he was surprised by "new arguments" in a Reply and that it would be unfair to not allow a response, while at the same time asserting that the MAC can raise "new issues/arguments" as a basis for denial while insureds/providers are precluded from responding and introducing evidence to rebut the "new issues/arguments." The Secretary's motion should be denied. To the extent the Court allows the Secretary's supplemental paper, a reply by VWG is attached as Exhibit A.

Dated: August 26, 2022 Respectfully submitted,

/s/Daniel Z. Herbst

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## **CERTIFICATE OF SERVICE**

I hereby certify that on August 26, 2022, a true and correct copy of the Plaintiff's Opposition to Defendant's Motion for Leave to File Surreply was filed via the Court's CM/ECF system and served upon all attorneys of record.

/s/Daniel Z. Herbst

Daniel Z. Herbst (Bar No. 17510)